Translation

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(1)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B 3732	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP98/06945	International filing date (*day/month/year*) 03 November 1998 (03.11.98)	Priority date (*day/month/year*) 03 November 1997 (03.11.97)
International Patent Classification (IPC) or national classification and IPC A61M 5/14, 5/38		
Applicant BECTON DICKINSON MEDIZINTECHNIK GMBH & CO. KG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 31 May 1999 (31.05.99)	Date of completion of this report 08 February 2000 (08.02.2000)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP98/06945

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

☐ the international application as originally filed.

☒ the description, pages 1 - 16, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☒ the claims, Nos. 1 - 18, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig 1/6 - 6/6, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 2, 14 - 18

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 2, 14 - 18 are so unclear that no meaningful opinion could be formed *(specify)*:

See Supplemental Box

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III

The novelty, inventive step or industrial applicability of dependent Claims 2 and 14-18 cannot be meaningfully assessed at present for the following reasons:

Claim 2 does not contain any additional technical features that would further restrict the subject matter of the claim. The feature in the characterising part of Claim 1 is merely repeated using different wording.

Claim 14 defines features of a preferred embodiment of the infusion apparatuses as per Claims 1-13, used to make it easier to pump liquid into the drip-chamber. However, in view of the description, it is totally unclear how these features are implemented and from where their function is derived. In particular, it is not clear how the feature **a guide element is adjacent to the liquid filter** should be understood. The description gives contradictory information on the meaning of the expression **adjacent**: on page 7, lines 9/10, it is stated that the filter **is pressed against** the guide plate from below **during pumping**. It can be deduced therefrom that otherwise the filter is not pressed against the guide plate. However, it is stated on page 13, lines 10-13, that the whole of the lower surface of the filter **lies** on the lower surface of the guide plate (see Figure 6).

Likewise, the effect of the guide plate is not clear, as it is not understandable how air passage is increased when pumping in the direction of the liquid container. If it is assumed that the filter lies on the guide plate at least during pumping, the filter pores are closed by the

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III

walls located between the recesses (34), reducing the effective air passage surface. How can this increase air passage? Is this due perhaps to other features of the guide plate? It seems that essential features have not been disclosed.

Pursuant to PCT Article 34(4)(a)(ii), the International Preliminary Examining Authority has not examined the features of Claims 2 and 14 for compliance with PCT Article 33(1). Since Claims 15-18 are dependent on Claim 14, these claims cannot be examined either.

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	4, 5, 8, 9, 10, 12	YES
	Claims	1, 3, 6, 7, 11, 13	NO
Inventive step (IS)	Claims		YES
	Claims	4, 5, 8, 9, 10, 12	NO
Industrial applicability (IA)	Claims	1, 3-13	YES
	Claims		NO

2. Citations and explanations

This report makes reference to the following documents:

D1: EP-A-0 001 114
D2: GB-A-2 044 620
D3: US-A-4 413 990
D4: WO-A-96/29104.

1.1 Document D1 is considered the prior art closest to the subject matter of Claim 1; insofar as this claim can be understood (see Box VIII), that document discloses the following features of the claim (the references between parentheses relate to that document; see, in particular, Figure 3):

Infusion apparatus with a tube (38) that leads from a patient to the outlet end of a drip-chamber (36) and that can be closed, "in particular", by a tube clamp (40, Fig. 1) for dosing and closing, a puncture part (28) tightly mounted on the inlet end of the drip-chamber (36) and provided with a puncture pin (12, 18) intended for puncturing an infusion solution bottle stopper, a liquid channel (32) extending through the puncture pin (12, 28) and opening on

the one hand into the drip-chamber (36) and on the other hand into the front region of the puncture pin (34), as well as an air channel (50) next to the liquid channel (32) "preferably" provided with an air filter (46) and opening into the ambient atmosphere on the one hand in the front region of the puncture pin (12, 28) and on the other hand in the rear region of the puncture part (28), connecting the inside of the infusion solution bottle with the ambient atmosphere when the puncture pin (12, 28) is inserted into the stopper of the infusion solution bottle, allowing outside air to flow into the infusion solution bottle when liquid flows over into the drip-chamber (36) (page 21, lines 25-29), a fine-pore liquid filter (64) being arranged in the path of the infusion solution from the puncture pin (28) to the tube (35), and means being provided for at least partially venting and filling the drip-chamber (36) with infusion solution before infusion starts (page 21, lines 8-13), the liquid filter (64) being arranged above the bottom of the drip-chamber (36) at a distance therefrom that does not prevent air from entering the tube (38) even when the tube (38) is not closed (page 22, lines 23-26).

Since there is no difference between the infusion apparatus known from the closest prior art and the subject matter of Claim 1, this claim does not meet the novelty requirement of PCT Article 33(2).

1.2 It should also be noted that the infusion apparatuses depicted in Figures 6, 12 and 15 of

2.2 The features of dependent Claim 4 are known from the infusion apparatuses disclosed in documents D3 and D4; cf. document D3, in particular column 6, lines 31-35, and column 5, lines 10-12; D4, Fig. 1, feature 15, and page 8, first and third paragraphs. Consequently, it was obvious to a person skilled in the art to also apply these features to an infusion apparatus as per document D1, to like effect, and thus to arrive at an infusion apparatus as per Claim 4.

Dependent Claims 5 and 8 concern minor alterations to the design of the infusion apparatus as per Claims 4 and 1 which lie within the scope of what a person skilled in the art routinely does, on the basis of familiar considerations, especially since the advantages achieved thereby are easily foreseeable. Consequently, the subject matter of Claims 5 and 8 does not involve an inventive step either.

The subject matter of Claim 12 consists in a pore size range of the liquid filter that cannot be found in document D1. The selection of such a range can be considered inventive, however, only if it has unexpected effects or properties in relation to the pore size value range disclosed in D1. However, the application does not indicate such effects or properties, and therefore the subject matter of Claim 12 is not considered inventive either.

3.1 Document D3 is considered the prior art closest to the subject matter of Claim 9. It discloses (the references between parentheses relate to that document):

Infusion apparatus with a tube (18b) that leads from a patient to the outlet end of a drip-chamber (40+26) and that can be closed, in particular, by a tube clamp (46) for dosing and closing, a puncture part (14+18a) tightly mounted on the inlet end (24) of the drip-chamber (26) and provided with a puncture pin (14) intended for puncturing an infusion solution bottle stopper, a liquid channel extending through the puncture pin (14) and opening on the one hand into "the drip-chamber (26)" and on the other hand into the front region of the puncture pin (14), as well as an air channel (25) next to the liquid channel preferably provided with an air filter, a fine-pore liquid filter (34) being arranged in the path of the infusion solution from the puncture pin (14) to the tube (18b), the liquid filter (34) being arranged in "the drip-chamber (26)", preferably on its bottom (36), an auxiliary drip-chamber (40) being provided between "the drip-chamber (26)" and the tube (18b), as well as means (42) for at least partially venting and filling the auxiliary drip-chamber (11) with infusion solution before infusion starts (see also column 6, lines 12-30).

The subject matter of Claim 9 differs from that known infusion apparatus essentially by the venting device on the puncture pin. The subject matter of Claim 9 should therefore be considered novel (PCT Article 33(2)).

However, venting is not required in the known

infusion apparatus, since it uses a flexible infusion container in the form of a bag. If a person skilled in the art also wanted to use glass bottles or the like, it would have been obvious to him to provide a vent for the bottle. Since vents on puncture pins are generally known (see D1), an inventive step cannot be derived from the presence of this feature in Claim 9 (PCT Article 33(3)).

3.2 It is noted that the feature **buret** (26) fulfils the same function as the drip-chamber 11.

3.3 The subject matter of Claim 10 is also disclosed in document D3, and therefore the infusion apparatus as per Claim 10 also does not meet the requirements of PCT Article 33(1) for lack of inventive step (PCT Article 33(3)).

4. The infusion apparatus as per Claims 1 and 3-13 is industrially applicable (PCT Article 33(4)).

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1.1 Independent Claims 1 and 9 do not meet the requirements of PCT Article 6 because their subject matter is unclear.

The feature **"is prevented.. by further measures"** is unclear because it suggests to the reader that further features are provided to prevent air from entering besides those defined in the characterising part of the claims. It can be assumed that the "measures" mentioned in the preamble of the claims are precisely those features disclosed in the characterising part of the claims. This should have been expressed more clearly by a corresponding formulation (characterised in that the measures..., or the like). The expression **"is prevented.. by further measures"** was not taken into account when assessing the novelty and inventive step of the claims.

1.2 Moreover, independent Claims 1 and 9 are unclear (PCT Article 6) if the description is used to interpret them. On page 9, lines 15/16, it is suggested that the **retaining ring 23** is a feature of the invention (**according to the invention**). However, the ring as such is not defined in the independent claims, creating a contradiction between the claims and the description (PCT Guidelines, PCT Gazette of 29 October 98, Section IV, Chapter III, 4.3). The use of the expression **according to the invention** on page 8, line 20, also leads to a similar contradiction.

VIII. Certain observations on the international application

2.1 In Claim 17, the wording (in German) "**dass die Leitplatte einer** Ausdehnung... aufweist" is incomprehensible (PCT Article 6). It should read "**Leitplatte eine Ausdehnung**".

2.2 Claim 18 concerns, *inter alia*, an infusion apparatus as per Claim 13. However, it defines features of the recesses, which are defined for the first time in Claim 14. To be correct, this claim should refer to one of the Claims **14** to 18 (PCT Article 6).

3. The features in Claims 1, 4, 8, 9, 11, 13, 14, 16 and 17 that follow the expressions **in particular, preferably, suitably,** do not have a limiting effect on the scope of protection of the claims. These features should be considered optional (PCT Guidelines, PCT Gazette of 29 October 1998, Section IV, Chapter III, 4.6).